DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 22, 2014

Stryker Trauma AG
Elijah N. Wreh
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K143138
Trade/Device Name: AxSOS 3 Ti Locking Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 31, 2014
Received: November 7, 2014

Dear Mr. Wreh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143138

Device Name
AxSOS 3 Ti Locking Plate System

Indications for Use *(Describe)*
The AxSOS 3 Ti Locking Plate System is intended for long bone fracture fixation.
Indications include:
- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- Non-unions and malunions
- Normal and osteopenic bone
- Osteotomies

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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CONTACT PERSON: Elijah N. Wreh
Regulatory Affairs Specialist

Date Prepared: December 18, 2014

DEVICE

Name of Device: AxSOS 3 Ti Locking Plate System

Common or Usual Name: Bone Plates
Bone Screws

Classification Name: Single/multiple component metallic bone fixation appliance and accessories 21 CFR §888.3030

Smooth or threaded metallic bone fixation fastener 21 CFR §888.3040

Regulatory Class: II

Product Codes: HRS: Plate, Fixation, Bone
HWC: Screw, Fixation, Bone

PREDICATE DEVICE: Synthes (USA) LCP Proximal Humerus Plates, Long (K041860)
No reference devices were used in this submission.

DEVICE DESCRIPTION

This Traditional 510(k) submission is being supplied to the U.S. FDA to obtain authorization to market additional plates within the AxSOS 3 Ti Locking Plate System. The AxSOS 3 Ti Locking Plate System includes anatomically contoured monoaxial locking plates. The 5.0mm System consists of the Distal Lateral Femur Plates (K123964). The 4.0mm System comprises the Proximal Lateral Tibia Plate, Proximal Medial Tibia Plate, Distal Medial Tibia and Distal Anterolateral Tibia Plate (K123964 & K141121). This submission adds the Proximal Lateral Humerus Plate to the 4.0mm System of the AxSOS 3 Ti Locking Plate System. The system includes three (3) types of

screws available in various diameter and thread length: locking, cortical, and cancellous (K123964 & K133440). The plates have been designed with holes that can accommodate either a locking or non-locking screw at the peri-articular end and along the shaft of the plate. The plates also have an oblong hole located at the metaphyseal junction used to aid in positioning. The subject components will be available sterile and non-sterile.

The associated accessories include:

- Aiming Block, Proximal Lateral Humerus, Right
- Aiming Block, Proximal Lateral Humerus, Left
- X-Ray Template, Proximal Lateral Humerus
- Tag for Proximal Humerus Plate Insert
- Proximal Lateral Humerus Insert

INDICATIONS FOR USE

The AxSOS 3 Ti Locking Plate System is intended for long bone fracture fixation.
Indications include:

- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- Non-unions and malunions
- Normal and osteopenic bone
- Osteotomies

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The device comparison showed that the subject device is substantially equivalent in intended use, design and operational principles to the previously cleared Synthes (USA) LCP Proximal Humerus Plates, Long (K041860). The subject plates are substantially equivalent to the predicate device in regards to intended use, design, materials, and operational principles for use for long bone fracture fixation.

PERFORMANCE DATA

Non-Clinical Test

Non-clinical laboratory testing was performed on the worst case subject plates to determine substantial equivalence. The following testing was performed:

- *"Standard Specification and Test Method for Metallic Bone Plates"* as per ASTM F382-99 (reapproved 2008)

Biomechanical testing was conducted to evaluate the bending fatigue properties as per ASTM F382-99 (reapproved 2008) to compare the mechanical properties of the subject plates to the previously cleared Synthes (USA) LCP Proximal Humerus Plate, long (K041860). A fracture gap model was used to set up the plates for the determination of fatigue properties.

Testing demonstrated that the subject plates are substantially equivalent to the marketed predicate device.

Biocompatibility Testing

The biocompatibility evaluation for the subject AxSOS 3 Ti Locking Plate System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The plates are categorized as per EN ISO 10993-1:2009 (E) as "Implant Device" with "Tissue/bone" contact duration > 30 days. The material is Titanium alloy (Ti6Al4V-ELI) as per ASTM F136.

All Class II instruments are categorized as per EN ISO 10993-1: 2009 (E) as an "Implant Device" with "Tissue/bone" contact of duration <24 hours.

Animal Study

Animal testing was not required for this submission.

Clinical Testing

Clinical testing was not required for this submission.

CONCLUSIONS

The subject device has the same intended use and similar technological characteristics as the predicate device. The non-clinical laboratory data support the safety of the subject AxSOS 3 Ti Locking Plate System and demonstrate that the subject device should perform as intended in the specified use conditions. Therefore, the subject AxSOS 3 Ti Locking Plate System is substantially equivalent to the predicate device identified throughout this submission.